

K230444 Talee, Talee PostOpJun 22, 2023
121 days to decisionK230444 · Product code: **MVA** · Neurology
Source: <https://www.510kdatabase.net/k230444/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Feb 21, 2023
Decision date	Jun 22, 2023
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Invent Medical USA, LLC
Location	Warminster, PA, US
Contact	Jiri Rosicky
510(k) history	3 submissions · 3 cleared · 2022-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230444/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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